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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,232

08/26/2003

Edward P. Ingenito

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6203

25181

7590

06/01/2009

FOLEY HOAG, LLP  
PATENT GROUP, WORLD TRADE CENTER WEST  
155 SEAPORT BLVD  
BOSTON, MA 02110

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/649,232	<b>Applicant(s)</b> INGENITO, EDWARD P.	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3763

## **DETAILED ACTION**

### ***Response to Amendment***

Amendment filed on 3/26/09 has been entered.

Claims 1-13, 15-18 are present for examination.

Claim 14 is cancelled.

Applicant's arguments filed have been fully considered but are not persuasive. Therefore, claims 1-13, 15-18 are rejected in the same ground of rejections as set forth in the office action mailed 11/26/08.

### ***Terminal Disclaimer***

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 15-18 are rejected under 35 U.S.C. 103(a) as obvious over Perkins et al. (US 6,287,290).

Perkins discloses an optional methods, systems and kits for lung volume reduction that includes advancing the bronchoscope (see 2: 15+ and 8:18+) and introducing composition or biological material comprising a sealing (introducing fibrin glue, see col. 10:35+) or occluding a plug 282 containing anti-surfactant (collagen hydrogel) to collapse the diseased alveolar (CLT) region (see 10: 37+). The collapsed region will be sealed by methods include the use of suturing, gluing energy mediated tissue

Art Unit: 3763

adhesion etc..., such as tissue adhesive, such as fibrin glues (2, 35+) or using a plug of hydrated collagen hydrogel (biological material for promoting fibrosis and increasing surface tension).

Thus, it would have been obvious to a person of ordinary skill in the art to try the sealing or occluding plug method in an attempt to collapsed tissue region, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, the method of sealing or occluding plug as suggested in the prior art, it would have been obvious to use for collapsing or lung volume reduction.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins in view of Edwardson et al. (US 5,739,288).

Perkins meets the claim limitations as described above but fails to disclose the use of fibrinogen and a fibrinogen activator such as thrombin.

Edwardson discloses a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins 10:40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson et al. in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery time.

Applicant also admitted that the activators are known in the art and include thrombin (page 7, lines 23+ of Specification).

Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins in view of Edwardson and further in view of Antanavich et al. (US 5,814,022).

Perkins meets the claim limitations as described above but fails to include the composition comprising 3-12% fibrinogen.

Art Unit: 3763

Edwardson discloses a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins 10:40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery time.

Perkins in view of Edwardson meets the claim limitations as described above but fails to include the composition comprising 3-12% of fibrinogen.

Antanavich discloses a method and apparatus for applying tissue sealant that includes that use of an adhesive protein solution having a fibrinogen content of from 3 to 12% with clot promoting factor XIIIa and further notes that one reason for this arrangement is that the strength of the sealant is proportional to the fibrinogen concentration. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins 10: 40) and Antanavich teaches an enhanced fibrin sealant composition a combination is proper. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to incorporate the concentration of fibrinogen as taught by Antanavich into the invention of Perkins in order to have an adhesive protein solution that is less prone to clogging before administered to the therapeutic site as taught by Antanavich. Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226

Art Unit: 3763

(Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 15, 22, 23, 31, 55, 60 of copending Application No. 10/069307; claims 1-18 of copending Application No. 10/649,232; claims 1-11 of US Patent No. 6,610,043; claims 1-32 of US Patent No. 6,682,520; claims 1-4 of US Patent No. 7,300,428.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are fully disclosed and covered by the claims of the copending application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments filed 08/28/07 have been fully considered but they are not persuasive.

1. Applicant argues that Perkin does not target the alveolar region of the lung.

In response, Perkins clearly discloses that lung volume reduction is performed by collapsing a target lung tissue segment, ..., i.e., segment of the branching bronchus which deliver to and receive air from the alveolar regions of the lung, col. 6, lines 34-39, (emphasis added).

According to Fig. 1, Application shows that the target region is same as location with the Perkin in Fig. 4A below.

Art Unit: 3763

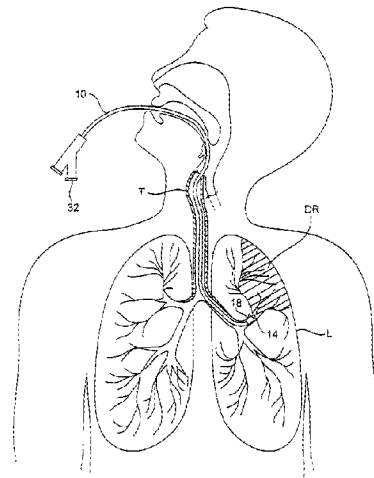
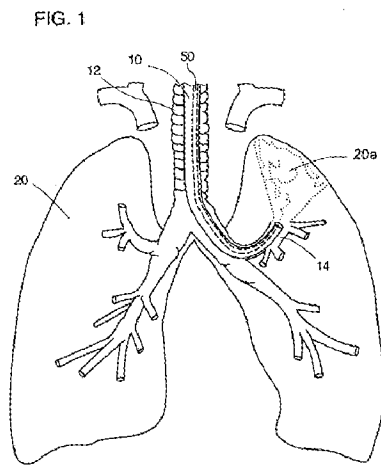


FIG. 4A

2. Applicant argues that Perkin teaches optionally sealing or occluding an air passage leading to the collapsed region of the lung by "delivering a plug..., typically at [sic] partially hydrated collagen hydrogel..." **after** the lung has been collapsed by vacuum aspiration or the application of external force. The plug is delivered to the lung bronchus and used to seal the air passage leading to the target lung segment (col. 9, lines 24-29; col. 10, lines 37-58, and Fig. 4C).

In response, Perkin does not disclose that delivering a plug, or hydrated collagen hydrogel material **after** the lung has been collapsed. Perkin clearly discloses that the method of sealing or occluding the air passage leading to the collapsed tissue region CLT. The sealing can be performed in a variety of ways, including suturing, gluing, energy mediated tissue adhesion, and the like. In a preferred aspect of present invention, a sealing catheter 280 can be used to deliver a plug 282, typically at partially hydrated collagen hydrogel, col. 10, lines 37-45. In other words, Perkin introduces a plug 282 includes hydrated collagen (adhesive material or anti-surfactant) targeted to CLT (diseased alveolar) region and causes collapse of the diseased alveolar region.

It is noted that the features upon which applicant relies (i.e., delivering a plug..., typically at partially hydrated collagen hydrogel..." **after** the lung has been collapsed by vacuum aspiration or application of external force) are not recited in the rejected claim(s). Although the claims are interpreted

Art Unit: 3763

in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion, the Applicant's claimed methods relate to reducing lung volume in a patient by introducing material through a bronchoscope into a diseased alveolar region within the targeted region; introducing a composition comprises an anti-surfactant into the diseased alveolar region causes collapse of the diseased region and one promotes adhesion between the one portion of diseased alveolar region to another portion of the diseased alveolar region. Similarly, Perkin discloses the method for lung volume reduction is performed by collapsing the target lung tissue segment (such as diseased alveolar region). The method comprises introducing the catheter into the target region for enhancing the aspiration and collapse of the target lung tissue segment, col. 2, line 15-col. 9, line 22). Beside that, Perkin further discloses that there is another method or optionally method comprises sealing or occluding the air passage leading to the collapsed tissue region CLT. For example: the sealing can be performed in a variety of ways, including suturing, gluing, energy-mediated tissue adhesion, and the like. In other words, the sealing can be provided some anti-surfactant material (fibrin glue or other suitable sealant) for adhering two tissues together, col. 10, lines 37-41).

Or other method that delivering a plug 282 includes a hydrated collagen hydrogel (anti-surfactant or adhesive material) causes the collapsed tissue region, col. 10, lines 41-45. Since the anti-surfactant (hydrated collagen hydrogel) contained in the plug 282, as known that, collagen hydrogel can be performed function such as sealing or adhering two tissues of diseased lung region together.

Therefore, one skill in the art would recognize that the Perkin can be read all claimed subject matter of the invention.

### 3. Response to the argument of claims 2-13 under 35 U.S.C. 103 rejections.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).



Art Unit: 3763

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763